DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Rec'd 3/26/98 jl

MAR 13 1998

Mr. Mark R. Sigel
The Traveling Herbalist
6168 Olson Memorial Highway
Golden Valley, Minnesota 55422

Dear Mr. Sigel:

This is in response to your letters of December 8, 1997 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that The Traveling Herbalist is making the following claims, among other claims, for the products:

Echinacea (with the dietary ingredients: certified organic or wildcrafted Echinacea (Echinacea purpurea) root powder, 450 mg. per VEGICAP)

"Promotes well-being during cold and flu season"

Echinacea (with the dietary ingredients: certified organic or wildcrafted Echinacea angustifolia root, Echinacea purperea root, flower head and seed)

"Promotes well-being during cold and flu season"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to

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regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Minneapolis District Office, Office of Compliance, HFR-MW340

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456:jel:3/13/98:docname:56118.adv:disc26

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

DEC 10 1997

This notification is being filed on behalf of **The Traveling Herbalist** which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: **6168 Olson Memorial Highway, Golden Valley, MN 55422.** This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. 101.93. The dietary supplement product, the label of which contains these statements, is **Echinacea.**

The text of each structure function statement for which notification is now being given is as follows:

Statement 1: Promotes well-being during cold and flu season.

The following summary identifies the dietary ingredients(s) or supplement(s) for which a statement has been made:

Statement No:	Identity of Dietary Ingredient(s) for Which Each Statement Is Made
1	Certified organic or wildcrafted Echinacea (Echinacea purpurea) root powder, 450 mg. Per VEGICAP.

I, **Mark Sigel,** am authorized to certify this notification on behalf of **The Traveling Herbalist.** I certify that the information presented and contained in this Notification is complete and accurate, that **The Traveling Herbalist** has substantiation that each statement is truthful and not misleading.

Date Signed: December 8, 1997 By: Mark R. Sigel Vice-President
[Name]
[Title]

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Date Signed: December 8, 1997 By: Mark R. Sigel Vice President
[Name]
[Title]

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